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July 23, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Rm. 1-23
Rockville, MD 20857
Attn: Desk Officer for FDA

Re: Docket No. 98N-0222
Proposed Rule
Dissemination of Information on Unapproved/New Uses
for Marketed Drugs, Biologics, and Devices
Federal Register Notice, June 8, 1998 (Volume 63, Number 109)

Dear Sir/Madam:

Medtronic is the world's leading medical technology company specializing in implantable and interventional therapies. The Drug Delivery Business develops therapies and products to treat intractable neurological diseases, many of which are rare conditions such as km-actable spasticity and pain and ALS.

We respectfully request FDA to consider the following comments:

Subpart A - General Information:

Scope:

We propose FDA grant to manufacturers exemptions to the requirements set forth in this rule if the "new use" has been accepted as "standard medical practice", i.e. indications that are listed in the USP DI, or Hospital Formulary, etc.

Definitions:

Scientific/medical journal: The definition stipulated in the proposed *rule is very narrow in scope* by limiting to articles published in journals listed in Index Medicus and excluding Special Supplements. Manufacturers should be allowed to disseminate unabridged articles on new uses if the publication meets the criteria of scientific soundness.

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We propose that FDA not exclude dissemination of "Special Supplements" as long as the special supplement meets the criteria of being fair, balanced and objective and as long as it includes information on other relevant therapies/treatments for the off-labeled indication,

Subpart D - Agency **Action on a Submission:**

We proposed that FDA would automatically grant an exemption from a supplemental application for the "off-label" use if such indication is for a rare disease or condition, if it has been designated by FDA as such. As stipulated in the Orphan Drug Act, a rare disease or condition is one which occurs so infrequently in the United States that them is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.

We urge FDA to exercise discretion when considering "new use" information in a publication if the primary focus of the piece is on the approved **use(s).** We urge the Agency to consider exempting the pro-approval and reporting requirements in these cases. One example is post approval studies with long term "effectiveness" data on patients. Many of these patients may have conditions that are outside the approved indication(s). Very often the data is derived from "real life" situations and would be particularly important for health coverage decisions. FDA would serve the public well if less burdens are imposed.

Subpart C - Manufacturer's Submissions, Requests and Applications:

We urge the Agency to consider the incremental gain in public health protection as ***compared to the resources*** and burden on the Agency and industry that would be required to review and approve submissions and maintain records, The burden estimated in the proposed rule may not be an accurate reflection of the actual burden associated with the collection of information and recordkeeping to comply with this regulation.

Medtronic appreciates the opportunity to comment on this proposed rule. We urge the FDA to consider these comments in an effort to clarify requirements for timely dissemination of results of medical research to health professionals and payers.

M-needy,

Winifred Wu/ka

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